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Laura Elizabeth Broughton, Student

Linda Alexander, EdD, Committee Chair

Corrine Williams, ScD, MS, Director of Graduate Studies

Overdose Education and Naloxone Distribution by Board-Certified Pharmacists in Five
Eastern Kentucky Counties

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the
requirements for the degree of
Master of Public Health
in the
University of Kentucky College of Public Health
By
Laura Elizabeth Broughton
Pleasureville, Kentucky

Lexington, Kentucky
April 8, 2016

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Project Abstract:

The Coalition of Kentucky Health Professionals Against Substance Abuse (CKHPASA) is a professional organization uniting members of the various health professions against a rising tide of substance abuse in the state of Kentucky. In 2013, Kentucky ranked 3rd in the United States for highest number of drug overdose fatalities. Previously under the scourge of the prescription opioid epidemic, the state of Kentucky is now seeing rising numbers of overdose deaths related to heroin use, which is an opioid that works similarly to morphine and prescription pain medications.

Naloxone is a life-saving antidote for opioid related overdoses and evidence has shown dramatic decreases in overdose related deaths as access to at-home naloxone increases. Senate Bill 192, signed into law in 2015, grants Kentucky pharmacists the ability to dispense naloxone to patients requesting it at their pharmacy without an expressly written physician's prescription. The pharmacists must be certified to dispense naloxone by the Kentucky Board of Pharmacy and enter into a collaborative care agreement with a local physician to be capable of dispensing naloxone in this manner.

In eastern Kentucky in rural Appalachia, access to physicians, emergency services, and hospitals is diminished compared to suburban and urban areas of the state. In these disparate communities, at-home naloxone obtained at the local pharmacy will reduce overdose related mortality and morbidity by increasing access to the antidote and overcoming barriers to timely emergency response. In the context of this grant, CKHPASA will utilize board-certified pharmacists in collaborative care agreements with local physicians to provide addicts and their loved ones in Bell, Breathitt, Floyd, Harlan, and Perry counties with access to naloxone as a harm reduction strategy.

These five counties were among the highest ranked in overdose death rate per capita in the state of Kentucky in 2013 and are the focus of this intervention. This intervention is modeled after two successful Overdose Education and Naloxone Distribution (OEND) programs. It will provide naloxone via auto-injector to addicts or their loved ones, the necessary education to successfully administer the naloxone in the event of an overdose situation, and information on resources in the area to assist the opioid addict on their journey toward lasting sobriety along the Transtheoretical Model of Change.

Overdose Education and Naloxone Distribution by Board-Certified Pharmacists in Five
Eastern Kentucky Counties

Laura E. Broughton

University of Kentucky College of Public Health

A. TARGET POPULATION AND NEED

For many years, Kentucky has been near the top of the national list for drug overdose deaths. In 2013, Kentucky ranked third in the nation for drug overdose deaths: a staggering 23.6 per 100,000 persons succumbing to fatal drug overdose. This figure has quadrupled since 1999 and reflects a well-documented prescription drug epidemic.¹ Since the transition to heroin from prescription painkillers in Kentucky, heroin overdose deaths have skyrocketed, jumping 55% between 2012 and 2013 and now accounting for 31.9% of all overdose deaths in the state.^{2,3}

Although the greatest number of overdose deaths occur in Kentucky's largest population centers, including Louisville (Jefferson County), Lexington (Fayette County), and Northern

County	Overdose Deaths Per 100,000
Bell	93.2
Breathitt	44.3
Floyd	43.9
Harlan	42.1
Perry	42.8
Statewide	23.8

Kentucky (Kenton, Boone, and Campbell Counties) many of the

Table 1

hardest hit counties per capita are much more likely to be rural and in Appalachian-designated counties in eastern Kentucky. In 2013, the counties with the most devastating burden of overdose deaths per capita included Bell (93.2 per 100,000), Breathitt (44.3), Floyd (43.9), Perry (42.8), and Harlan (42.1).³

The Kentucky General Assembly passed Senate Bill 192 in 2015 as a response to the burgeoning statewide heroin epidemic. The bill, signed into law by then-governor Steve Beshear on March 25, 2015, contained multiple provisions targeting heroin abuse. In addition to stricter penalties for drug traffickers and a shifting focus from imprisonment to treatment for addicts, these provisions were also permitted pharmacists to dispense naloxone, which a life-saving opioid antidote, without a prescription.^{4,5}

Naloxone may be requested by an addict or their loved ones to keep on hand in the event of an accidental overdose.⁶ Nowhere will this new provision of SB 192 be more helpful than in eastern Kentucky. In particular, this intervention focuses on the five counties with the highest rates per capita of overdose related death: Bell, Breathitt, Floyd, Perry, and Harlan.

In addition to the staggering per capita overdose death figures, the counties listed above are also grappling with extraordinary poverty rates. Bell County, which also topped the per capita overdose list, is nearly double the statewide poverty rate (see Table 2). The other counties in highlighted in the proposed intervention did not fare

Table 3

Table 2

County	Poverty Rate
Bell	35.7%
Breathitt	33.9%
Floyd	30.6%
Harlan	30.5%
Perry	26.9%
Statewide	18.8%

much better, and all of them exceed the 18.8% statewide poverty level.⁷ These poverty rates correlate to the unemployment rate, with all five counties exceeding the statewide

County	Unemployment Rate
Bell	9.2%
Breathitt	9.4%
Floyd	9.1%
Harlan	12.0%
Perry	8.5%
Statewide	5.6%

unemployment rate of 5.6%. In particular, Harlan County, which has been acutely

affected by the changing coal

economy, has an unemployment rate more than double that of the statewide average, at an astounding 12% (see Table 3).⁸

Table 4

County	Access to Mental Health Care (Persons in County : Number of Providers)
Bell	6971:1
Breathitt	847:1
Floyd	159:1
Harlan	4750:1
Perry	180:1
Statewide	621:1

All five counties also are underserved with regard to mental health care access. It is well documented that many individuals seek drugs and alcohol as a coping mechanism for untreated mental illness. Recent epidemiologic studies have shown that

between 30 and 60 percent of substance abusers are also determined to have a comorbid mental illness.⁹ In Harlan and Bell Counties in particular, for every individual mental health provider, there are thousands of residents in need of mental healthcare.¹⁰

All five counties are more decidedly rural than the remainder of the state, and this plays an important role in responding to and treating an overdose, where every second counts. Rural communities face a number of barriers in access to care, not least of which is the considerable distance to the nearest Emergency Medical Services (EMS)

County	Percent of Population in Rural Areas
Bell	62.5%
Breathitt	83.9%
Floyd	81.5%
Harlan	54.2%
Perry	74.1%
Statewide	41.6%

Table 5

station. Once EMS arrives and a dose of naloxone is administered, the victim will likely have to be taken to a hospital and stabilized.

Depending on the half-life of the opiate that the victim ingested, they may be given additional doses of naloxone in the hospital. For many residents in the most remote parts of these counties, hospitals are often even further away. The longer the travel time, the higher the risk of complications. In these situations in particular, having access to and administering naloxone while waiting on first responders to arrive on the scene could mean the difference between a full recovery and severe and lasting complications, or in the worst cases, death.¹⁰

In addition to disparities in mental health care access and the complications that rurality adds to reliable EMS transportation, the five highlighted counties are designated Health Professional Shortage Areas (HPSA) for primary care. A HPSA denotes that within this region of Kentucky there are not enough primary care physicians to adequately serve the population at risk. Due to the patient burden most primary care

physicians in the area face, and the relative distance from these counties to larger population centers with more advanced healthcare services, this provides naloxone-certified pharmacists an unprecedented avenue to advocate for their patients.¹¹

It should be noted that there are other resources besides pharmacies available in these communities where target populations can access naloxone. All five counties have health departments that may also dispense naloxone and physicians that can write prescriptions for it. There are also a number of grassroots organizations in the area working to provide patients with educational materials pertaining to the planned intervention. However, it is the position of the Coalition of Kentucky Health Professionals Against Substance Abuse (CKHPASA) that these resources by themselves are still inadequate in responding to this crisis.

Unlike most health departments and physician's offices whose office hours are restricted to daytime and weekday hours, pharmacies provide much greater access to care. As we have shown, it is important that when the need arises for a naloxone kit, they should be as widely available as possible—not just available during the traditional 9am-5pm weekday business hours. By offering this additional resource of naloxone distribution in these communities, we will reach more people than the current resources are able to reach, thus broadening the availability of this overdose antidote in the community.

All five counties within the intervention are members of the Appalachian High Intensity Drug Trafficking Area (HITDA) as established by the Office of National Drug Control Policy. HITDAs represent areas where a large amount of drug related activity is happening and where law enforcement and other agencies can best make an impact—

these counties are part of what has been designated as a “critical” region for drug use and trafficking.¹²

Survey data from a recent State Health Issue poll showed that 9% of all Kentuckians and 15% of all Kentuckians 18-29 know someone who is addicted to heroin², and Centers for Disease Control and Prevention (CDC) data suggest 5.2% of Kentucky high-school students use heroin.¹³ Given that this is statewide data and the counties in our intervention have overdose death rates that are twice the state level, and they are very geographically and socially close-knit communities,

we believe it is possible that 30% or higher of our target population knows someone who uses heroin. However, because these people may know the same addict or addicts and because the persons administering

County	Total Population (2014 est.)
Bell	27,778
Breathitt	13,409
Floyd	38,108
Harlan	28,163
Perry	27,597
Total	135,055

naloxone in the event of overdose are more likely to be close friends or relatives rather than casual acquaintances, the goal of this project is to reach 10% of the total population of the five intervention counties annually. The total population of all five counties is 135,055.¹⁴ Therefore, we would like to distribute naloxone kits to at least 1,350 people annually over the course of the three years of program implementation.

We will recruit patients to our program using a multi-modal mass media campaign. Print advertising will take place in all of the local newspapers, potentially with feature stories explaining the program within them. Flyers will be distributed at local businesses and churches. Due to the increasing prevalence of social media, a Facebook page will be set up by the Program Director to help recruit young people in particular to the project. We believe this connection is key, as young people are one and

Table 6

a half times as likely to know someone who abuses drugs as other adults (15% versus 9%). Small town life revolves around the gathering spots for community members, so by targeting advertising in those locations, by utilizing print media, and by bringing in the youth through social media, the majority of the population of these communities will be aware of the project's presence and will be able to find out more details in community forums held at the library or by calling a toll-free number to reach the CKPHASA.

Both those who abuse opioids themselves and are addicted as well as non-addicted family members will be targeted. We think that this will increase reach of the program as it will cover two of the more common scenarios of drug use. The first is alone in their home, which increases direct need for a caregiver to have access, as the addict can't administer their own dose of naloxone. The second is in a group setting with other addicts, where the addict could obtain the kit for themselves or for the benefit of the group.

Population data will continue to be monitored on an ongoing basis for changes in social determinants of health, overdose death rates, and other contributing factors to the high per capita prevalence of overdose. Continuous monitoring of the factors that make these communities ideal target factors will ensure our program continues to align with changing community needs.

B. PROGRAM APPROACH

Although the first pharmacist protocols for distribution of naloxone without a prescription (generally through collaborative care agreements [CCAs] set up in conjunction with local physicians) are a relatively new phenomena in the United States,

there is growing body of evidence to suggest that getting naloxone into the hands of lay people saves lives. A 2012 survey published in Morbidity and Mortality Weekly Report (MMWR) documented that an estimated 53,032 people had received training in overdose prevention and administration of naloxone through 188 community-based programs in 15 states and Washington DC. The programs received more than 10,000 reports of successful overdose reversals through administration of the naloxone by individuals who had received training. Ten thousand successful overdose reversals is a significant number of lives saved, even if some of the 10,000 are “repeat consumers” who have survived multiple overdoses.¹⁵

Naloxone (Figure 1) is a potent competitive μ -opioid receptor antagonist that is used to block the effects of opioids in the body, particularly in overdose situations. When naloxone is administered to someone undergoing an overdose, it will compete with the opioids present in the body for binding at μ -opioid receptors in the central nervous system. Because of their high affinity for the receptor, the naloxone will prevent the action of the opioid causing overdose (Figure 2) and thus stop the symptoms of overdose like respiratory depression and depressed heart rate.¹⁶

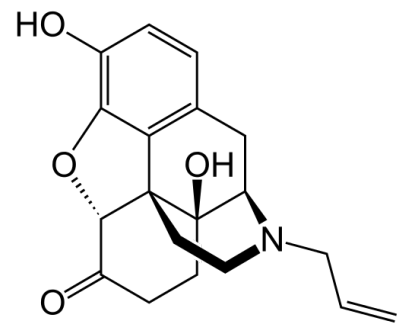
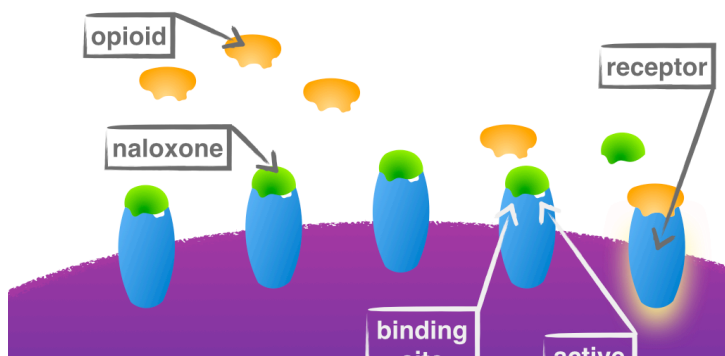


Figure 1

Additionally, as naloxone is a competitive antagonist and has nearly no agonist

properties, when it binds to μ -opioid receptors it elicits little to no action itself—it is only “active” in the presence of other opioids. This



concept is key for those keeping or potentially utilizing naloxone in the home, because in the event of accidental use of the product by a child or someone without opioids in their system, the drug is essentially benign and poses no serious risk.¹⁶

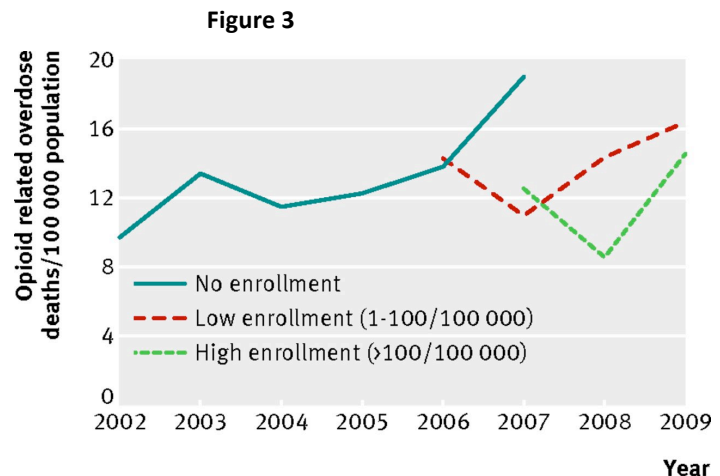
When administered intravenously, naloxone works to relieve the symptoms of overdose within two minutes. When administered intramuscularly, naloxone works to relieve symptoms of overdose within five minutes. When naloxone kits are sent home, they are typically for intramuscular use, or more frequently, intranasal use. Intranasal naloxone works almost as quickly as intravenous administration. The intranasal dose is usually contained in a prefilled single-dose syringe with a mucosal atomizer that often must be screwed into place before the dose is administered in the nose.¹⁶

Perhaps the most well-researched program with outcomes that show the evidence of the efficacy of community-based Overdose Education and Naloxone Distribution (OEND) programs is a time-series analysis conducted following implementation of OEND programs in Massachusetts. The researchers conducted an interrupted time series analysis of annual opioid related rates of overdose fatalities and utilization of acute care hospitals comparing communities and years where OEND was implemented with those where it was not. Researchers included the 19 communities in Massachusetts with five or more opioid related fatal overdoses in each year from 2004 to 2006, the two years prior to the implementation of OEND in Massachusetts. Training took place through six public health agencies in the state and was based on evidence-based curriculum developed by the Harm Reduction Coalition and the Chicago Recovery Alliance.¹⁷

In the Massachusetts OEND program, implementation was categorized in two ways. The first was based on median cumulative enrollment rate and from that, three groups were formed: groups with community-year strata that indicated no implementation, those below the median (low implementers), and those with enrollment rates above the median (high implementers). The second method involved determining if absolute population density of enrollment was associated with overdose rates. Communities were placed each year into three categories based on cumulative enrollment rate levels of no implementation, 1-100 per 100,000 population and >100 per 100,000 population.¹⁷

Even after adjustment for potential confounders such as demographics and substance abuse treatment utilization, rates of fatal overdose were 27% lower with low implementation communities and

46% lower with high implementation communities of the OEND. Among the 19 communities included in the study, 2912 individuals were enrolled in OEND programs over a three year period and 327 rescue attempts made using kits obtained from the program. Naloxone was successful in 98% of the rescue attempts, and the instances where it was not, the overdose victim received care from EMS and survived. This indicates the importance of the education component in recognizing the symptoms of overdose so that EMS was notified quickly enough to be impactful when intranasal naloxone administration failed.¹⁷



There are three types of OEND programs with various levels of evidence supporting the efficacy of their implementation. The first type, which has been in existence the longest and has the largest body of evidence supporting it, is the Initial Public Health Model. This model targeted the high-risk addict only and offered OEND in environments like needle exchanges. The second type is the Expanded Public Health Model, which expands to target “bystanders” in addition to the addict—loved ones, friends, family, etc. The Massachusetts OEND program is an example of the Expanded Public Health Model. The final type is the Health Care Model, which involves distribution of naloxone by health care systems.¹⁸

Pharmacists have an obligation to educate their patients on safe use of opioid medications—including those persons who use high doses of licit opioids daily who are also at risk of overdose. Part of opioid safety includes harm reduction that would come from those patients using opioids both licitly and illicitly being educated on the benefits of having naloxone on hand, and their caregivers being made aware of the signs of opioid overdose and instructed on how to administer naloxone. This education component already exists within the compulsory counseling offer pharmacy staff must make with each prescription purchase.²⁰ Because of their extensive knowledge about medication and training in patient consultation, pharmacists are an ideal resource for dissemination of OEND in a Health Care Model.

One of the first states in the United States to begin supplying naloxone through pharmacists in CCAs with physicians was Rhode Island. In response to Rhode Island having the highest overdose death rate per capita in the country at the time of the initiation of the program in 2011, the Rhode Island Board of Pharmacy approved a pilot

program in five Walgreens pharmacies in locations with high prescription opioid overdose mortality. After the pilot was completed, and in response to a growing problem with fentanyl overdose, the program spread to all Walgreens in the state and any other interested pharmacies. The Office of National Drug Control Policy has recognized this implementation of the OEND Health Care Model in Rhode Island as a leading public health-commercial collaboration, and an important distribution model for naloxone to address overdose risk in the community. While neighboring states reported significant increases in overdose related deaths between 2013 and 2014, Rhode Island's number of deaths increased only minimally.²⁰

There are limitations acknowledged in both the Massachusetts and Rhode Island studies. Firstly, overdose survival based on International Classification of Diseases (ICD) codes at the hospital require that those codes are properly documented by various hospital staff, and either neglect to classify or misclassification could have altered those success numbers. Additionally, in any given year overdose could occur in clusters—a “bad batch” of heroin laced with another drug could spur more overdose deaths and those numbers would inaccurately reflect typical overdose rates for the area. Particularly in Massachusetts, successful reversals were mainly obtained through self-report back to the program, so these numbers have the inherent issues that come with data derived from self-report methods. The Rhode Island study in particular acknowledge differences in insurance reimbursement among the different types of naloxone and how that could limit the program's effectiveness.

Adapting programs to suit your area's need is Step 4 of RAND's Getting to Outcomes and we think this is a pivotal step in this community and for this problem.²¹ It

is with this in mind that we propose Opportunities for Distribution of Naloxone in Area Pharmacies in Eastern Kentucky (OD-NAP EKY), a program that will blend the evidence basis of the Massachusetts Expanded Public Health Model OEND with pharmacist-dispensed naloxone in the Health Care Model from Rhode Island that was itself a “public health-commercial collaboration.” With the exception of the Rhode Island study, there are less instances of the efficacy of this model in community pharmacy based distribution because it is a new frontier in health care.

Based on the data of the reach and success of the Massachusetts OEND program as well as the Rhode Island program in target those areas with higher rates of overdose and then subsequently decreasing those rates, we are confident that the adaptations of these programs will meet the needs as previously defined in this community and are a good fit for the implementation setting. We also believe that our collective organization’s presence in every county in Kentucky indicates that we have the capacity to make these programs work seamlessly within the target populations.

The Massachusetts OEND put a strong emphasis on general education about recognizing overdose and also knowledge and self-efficacy in naloxone administration in the bystander population—which are crucial in a low health literacy population like our target population. General literacy is an issue in all of these counties, with a large percentage of adults scoring as “below basic” level of prose literacy, which means they could only interpret small pieces of uncomplicated written information.²²

County	% Adult Population with “Below Basic” Literacy
Bell	18
Breathitt	17

With this in mind, OD-NAP EKY will tackle the issue of low health literacy by adapting the Massachusetts OEND program and the Rhode

Floyd	15
Harlan	18
Perry	17
Statewide	12

Island OEND program to switch from intranasal naloxone administration to naloxone delivered by auto-injectors. Intranasal administration often requires

Table 7

attaching a nasal actuator to a prefilled syringe, which can be complicated, and then proper delivery to the nasal mucosa, which may be challenging.

Evzio®, the first auto-injector approved by the Food and Drug Administration (FDA), is a pocket-sized and portable dispensing device designed to administer a single dose of naloxone intramuscularly. The needle is housed within the device and is never exposed to the person administering the dose. The injection can even be administered through clothing. Once the outer case is taken off of the Evzio® device, the device begins to speak directions to the person administering the dose. First, it instructs them to prime the device for administration by removing the cap that covers the needle's trajectory. Then, it instructs them to place the auto-injector on the overdosing victim's outer thigh and press down hard. Once this happens, the needle is depressed down into the skin and the device begins a five second countdown. After the countdown completes, the needle retracts and the person administering the dose is instructed to remove the device and return the cap and outer case.²³

One main concern with the Evzio® injector has been that the small print on the device will not be helpful if a person is deaf or hard of hearing and cannot hear the directions as the device is speaking them. Kaléo Pharmaceuticals, which manufactures Evzio®, has larger leaflets that detail the administration process—complete with

pictures—that we will include in the naloxone kit specifically for our deaf and hard of hearing patients. Having pictures of the actual administration process will also benefit our other patients as well by helping to increase self-efficacy by being able to visualize what they are to do.²³

There will be five outreach points (one per county) when implementing our program, OD-NAP EKY. Each of those points will have a board-certified pharmacist to lead the pharmaceutical



piece of program implementation at the independent pharmacies they manage in that county. The first will be in Floyd County (county seat of Prestonsburg) and sits slightly isolated from the other four counties. The pharmacist-in-charge at Cooley Apothecary in Prestonsburg will lead the transition in Floyd County. The area covered by this outreach point is denoted in red on Figure 4.

The second and third outreach points will cover patients in Breathitt and Perry Counties. This region is denoted in green on Figure 4. The county seat of Perry County is Hazard, Kentucky. The pharmacist-in-charge at the Medicine Shoppe in Hazard will begin outreach for that community.. The pharmacist-in-charge at the Jackson Apothecary in Jackson, Kentucky, the county seat of Breathitt County, will lead our program implementation there.

The fourth and fifth outreach points will cover patients in Bell and Harlan Counties. This region is denoted in blue on Figure 4. Our basis of operation for Bell County will fall to the pharmacist-in-charge at the Walters Pharmacy Shoppe in Middlesboro, the largest city in Bell County. She will be joined in our program by the

pharmacist-in-charge at Donnell's Pharmacy in Baxter, which sits just outside of the county seat of Harlan in Harlan County.

At our five pharmacies, all pharmacists and all staff will be required to go through sensitivity training. This is so patients coming in to request naloxone will not be stigmatized or treated poorly because of their addictions, nor will the Health Insurance Portability and Accountability Act (HIPAA) be violated. HIPAA is an act passed by the United States Congress and signed into law in 1996 that protects patient information from unlawful dissemination.²⁴ The biggest concern for HIPAA violation because these are small towns is that pharmacy staff may either accidentally or maliciously tell other members of the community that another individual was seen at the pharmacy obtaining a naloxone kit. Not only is this a violation of that individual's right to privacy under HIPAA, but may cause additional stigma or duress. Therefore, it is crucial that all staff know that HIPAA must be followed to the letter and strict reprimand will be imposed on those who do not follow these requirements, including a minimum of immediate termination of employment upon the conclusion of an investigation or harsher punishment if such punishment for HIPAA violation is already in the employee manual at an individual pharmacy.

For all patients coming in to request naloxone, be they addicts themselves or the loved ones of addicts, training will be provided on how to administer naloxone, the existence of Good Samaritan laws, and the procedure following initial naloxone administration to reverse overdose. With regard to administration procedure, the pharmacist will employ the teach back method, wherein the patient is instructed to explain back to the pharmacist what they have learned. This will ensure that that the

patient understands procedure in its entirety and allows incorrect responses to be corrected immediately.

In particular, it is crucial that the person receiving the kit is made aware of the changes Senate Bill 192 made to KRS 218A.133. In particular, that they cannot be prosecuted for their good faith administration of naloxone to the overdosing patient; and secondly, that no arrests may be made if EMS and/or police come to the premises on an overdose related call. Even if everyone else in the room is in possession of drugs and/or paraphernalia, as long as they stay until the overdose patient receives treatment, they will not be charged with anything. There are a few exceptions to this rule—if the persons with the overdose patient are running from existing warrants, or if there is existing evidence outside of the overdose situation in which to charge them, for example.²⁵ This information will be given verbally, but also distributed in print form with dispensed prescriptions should the patient or loved one want it written down for easy recall later.

Additionally, accompanying the kits of information that are given with each dispensed naloxone prescription will be resources for additional services beyond the scope of this project that aim to assist the addict in addressing their addiction and underlying problems. We will give contact and program information for Karen's Place, a women's treatment facility in Louisa, Kentucky and Layne's House, a co-ed treatment facility in Pikeville, Kentucky. We will also include information on local Suboxone® and methadone maintenance clinics and/or physicians who provide these services. Part of the criteria for being included on this list of clinics is that the sites use a trauma-informed approach.

Information on access to local Department of Community Based Services (DCBS) offices will be provided to encourage those without health insurance to apply for Medicaid. Information will also be provided on local homeless shelters, crisis centers, and food banks. With these resources, it is understood that counseling provided by the pharmacist with dissemination of this literature will be considered a referral for services. If utilizing one of the listed services, when patients are asked what entity referred them to that service, they will be encouraged to name the referring pharmacy. While our goal with this program is to eliminate needless overdose deaths in the area, ideally a decrease in drug use in the area would decrease the emergent need for our services. A detailed logic model which contains information regarding these inputs and activities, in addition to the outputs and outcomes of this program can be found in Appendix A.

The five pharmacies mentioned will begin dispensing naloxone kits on January 1, 2017. This allows time for all staff pharmacists to obtain naloxone certification, product to be ordered, and publicity for the new program to be generated starting June 1, 2016. Staff pharmacists will be encouraged to take the University of Kentucky College of Pharmacy's course taught by Dr. Mimi Marquez, a member of the project team. Upon completion of the course, they will be able to apply for their certification from the Kentucky Board of Pharmacy. All pharmacy staff in each of the five pharmacies will attend sensitivity training by December 31, 2016. Additionally, coordination will be made with all local public libraries and schools to start placing our community education components onto their calendars beginning June 1, 2016. A more detailed analysis of the planning phase, and goals for implementation can be found in the attached Work Plan (see Appendix B).

Fidelity monitoring will take place under the direction of our Research Assistant's monthly reports on the number of kits dispensed at each pharmacy. If we are not meeting our targets then we will need to make changes in order to ensure the most efficacious implementation of this program in these communities. This will be a process of continuous quality improvement to ensure the fidelity of program, and will go hand-in-hand with other measures of implementation evaluation.

Beginning in June 2016, a Community Advisory Group (CAG) will begin meeting with community leaders from each of our target counties. Meetings will take place in Hazard, in Perry County, as the county most central to the area of outreach. During the formative phase, meetings will take place once monthly at the Community Center in Hazard. Beginning in 2017, meetings will be quarterly at the Hazard Community Center. We anticipate interest from the communities will grow upon seeing progress from the program, and because this is an area of high poverty and rurality, we will rotate meetings among the county seats annually until the program's conclusion. We also hope to bring on additional community members as time progresses and the program's impact is felt by the community.

Due to the tightknit nature of Appalachian communities, an advisory committee must be formed with individuals who represent and can articulate the values, customs, social norms and experiences of the community. We know that in many instances perceived "outsider" status of researchers or health educators can be a barrier to receiving care in small, rural Appalachian communities.²⁶ In overcoming this burden, our current CAG consists of the director of the Bell County Health Department, the pastor of Harlan Baptist Church, a physician practicing at Kentucky Rivers Medical Center in

Jackson, the founder of Hazard Hates Heroin, the Floyd County Judge-Executive, and the pharmacy managers charged with initiating implementation of the program. We also desire a combination of those with medical and public health knowledge and those without, including health practitioners other than pharmacists.

This is reflective of Strategies Guided by Best Practice for Community Mobilization. Strategy three is to establish a diverse organization with community leaders and residents. It goes on to say to challenge the organization to avoid partnering with the groups that seem automatic and focus on more unique approaches. These people who have significant influence within the community will be critical for getting our community mobilized, which is part of what geared our decision toward our five main CAG members.²⁷

Our Health Department member from Bell County will provide much needed perspective from a public health standpoint. She will also know about past interventions in these communities and what successes they had or did not have. The pastor from Harlan County has been with the families of the victims of this epidemic, held mothers as they cried over dead children and spouses as they said they didn't want to be lied to anymore. The pastor is a confidant for many of these people and will have as accurate a barometer on the situation as anyone in the community. The physician from Breathitt County will be crucial as a voice for community physicians to help make sure we are respecting clinical boundaries and assure other regional practitioners that this is addressing a need they are too overburdened to meet. The community leader who founded Hazard Hates Heroin lost his daughter to the epidemic and has been lobbying in Frankfort for legislative change in addition to holding town forums and bringing in

experts. Along with the pastor, he brings in the much needed voice for the people whom this situation is directly affecting. Because of his ties with legislators and with community residents, he will bring an outside perspective and will be able to add our program to the list of things he is promoting in the community to make a change. The Judge-Executive from Floyd County brings political leadership on the community level to the CAG, and a different perspective to the group aside from medical or personal—she sees daily how this is affecting her constituents from the cases brought to the courthouse and the near daily calls for EMS to houses where overdose is suspected.

There are several pharmacies within these communities in addition to the five we are initially piloting our intervention. We chose these five pharmacies because they are independent, family-owned pharmacies and their pharmacists will not be bound by the decisions of their corporate offices regarding what their pharmacists can or can't do. These local pharmacies are the best, in our estimation, to provide access to this OEND program. We have the necessary resources in these counties and in these pharmacies in order to begin and maintain this program with efficacy.

After funding has ended for this program, we hope to have curbed overdose rates by 45%, at a level similar to that of the Massachusetts OEND program over the course of three years with a similar level of implementation. It is our hope that due to the hard work being put in by our pharmacy staffs on the ground that the program will continue in a similar capacity even after CKHPASA is no longer using grant funding to do it. Because CKHPASA has members within the community that can speak to the education component, community wide education can continue on a volunteer basis in the absence of funding.

Regarding medication costs, we will continue to supply Evzio®, with manufacturer coupons on hand for prescription price assistance—however, these coupons will not work with government funded insurance programs like Medicare and Medicaid. During the course of the project we will also be working with our grassroots organization partners to lobby the Kentucky General Assembly and state Medicaid Managed Care Organizations (MCOs) to pay for one Evzio® auto-injector annually per Medicaid patient at no cost to the patient. This will not only impact the counties of our intervention but Kentucky citizens statewide who would not otherwise have access to afford to keep Evzio® on hand. It is our hope that by working on addressing cost issues in the beginning of the project, cost will not significantly impact sustainability of the project. Should these goals not be attained by the end of the grant period, a transition to a nasal actuator will happen in these stores that will more likely be covered by all plans and counseling on that route of administration will be a component of patient education.

C. PERFORMANCE MEASURES AND EVALUTION

The pharmacists and staff pharmacists at our stores will monitor the program for continuous quality improvement. Although naloxone is not a controlled substance, because of its unique position as a drug that can be prescribed by a pharmacist in a CCA with a physician, all dispensed prescriptions will be kept on the record as an addendum to the controlled substances log. The controlled substances log serves as a perpetual inventory that is maintained throughout the day by the pharmacist, and not only records quantities dispensed and received, but also the prescription numbers assigned each time they are dispensed. This will be the quickest way to track the naloxone dispensing record. Additional space will be included in the dispensing record

for the patient to sign saying that they have received counseling on knowing the signs of opioid overdose and how to administer naloxone using the Evzio® autoinjector.

Implementation can be evaluated by looking at the acceptance of pharmacists and pharmacy staff in the program. If our pharmacists and their staff are enthusiastically supportive of the program, they will be huge advocates in their community for sharing information about the program with community members. In small towns, pharmacies and their staffs are central figures in the healthcare system and as such, carry trustworthiness and clout that outsiders may not. Buy-in from the team will help ensure a successful implementation. Moreover, we hope that it will also secure the eventual spread of the program to other area pharmacies. To measure this, a ten-question survey has been developed to measure the pharmacy staff's perceptions of the program, how it is being implemented, and its effectiveness.

Our pharmacy teams are our seven-days-per-week, on-the-ground staff for this project and as such, their feedback is critical on how implementation of the project is proceeding. If any portion of implementation needed to be changed, it is they who will be aware of the need sooner than the Project Director, who will only be in each county twice monthly. As such, this survey will be administered to the pharmacy staff to gauge their baseline perceptions beginning June 1, 2016 and then re-administered every six months until the completion of the project on May 31, 2019. Data will be analyzed across all five sites but also aggregated by pharmacy to see how perceptions change at each pharmacy for the duration of the project. Should any changes need to be made, that will fall to the Project Director and the pharmacy manager at the site(s) in question will collaborate.

Process related outcomes can be evaluated by looking at acceptance of the programs within the communities they serve. One of the major concerns with OEND programs is that they encourage those who are using drugs to keep using them by providing them a “safety net”.²⁸ This will no doubt be a concern in this community. Reading articles in their local newspapers, including editorials, has shown that many community members are not accepting of programs that replace illicit use (like Methadone or Suboxone® clinics) and are not open-minded to other harm reduction measures like needle exchange programs. We will have to focus carefully on changing hearts and minds in this area. Measuring attendance at training sessions on the Evzio® auto-injectors at the local library and hopefully seeing growth will help. Engaging opponents to these harm reduction measures and asking for their feedback will be crucial. It is our hope that showing our data and explaining our information about rehabilitation and other helpful tools given with each kit will convince some of these opponents to join our cause.

We know that we must focus on explaining the benefits of harm reduction to these communities and how addiction is a non-linear process. At any given point, an addict will be moving through the phases of the Transtheoretical Model of Change. One relapse will send them back to the beginning again. Addiction is a disease where relapse is practically inevitable. NIDA says that 40 to 60% of drug addicts will relapse at some point during their recovery and start again. They compare this to the way that hypertension or type 2 diabetes worsens with non-adherence to medication therapy and finds these rates of “relapse” similar.²⁹ It is important that we stress the importance of meeting the addict where they are along their journey and saving a life for *today* so that

they might have that hope for *tomorrow*. Anecdotes from addicts in recovery about hitting their “rock bottom” that made them decide to move beyond those contemplative phases of the Transtheoretical Model of Change publish in local media might be one way to reach the population with real stories—particularly if “rock bottom” was realizing how close their actions brought them to death after surviving an overdose episode.

To see if those activities make a difference in the area, a fifteen question survey about community perception of addiction and overdose reversal will be administered to community members every six months, beginning June 1, 2016, until the completion of the program. Each administration of the survey will target 25,000 people (5,000 in each county) with an estimated return of around 500 surveys per county or 2,500 total. For the purposes of sustainability, we want to look at whether or not the community believes in the power of this program—if the community doesn’t like the program, it will be unlikely to be successful, both for the three-year duration of our grant and for the future. If significant gains are made in community acceptance over the course of the project, the positive trend from such data could potentially influence neighboring communities to adopt a similar model.

Additionally, we want to holistically evaluate the experience through interviews with patients who come into the pharmacy to obtain refill kits after having successfully used naloxone to save the life of a loved one. We want to know what the circumstances were, the overdose signs they noticed, their comfort and confidence in using the Evzio® auto-injector in the situation, and the outcome of the situation. Additionally, we will ask if the loved one or the patient has been able to start navigating the Transtheoretical Model of Change and by considering using the access to recovery or other provided resources

in our naloxone kits after their overdose experience. If there were any negative experiences during the overdose reversal situation, including with use of Evzio®, with EMS or law enforcement, or at the hospital, we hope to document that as well as something to keep in mind for continuously improving the program to make it a better experience for the caregivers tasked with administering naloxone in high pressure overdose situations. This qualitative analysis will be crucial to understanding the impact of this program on individuals within the community.

In the case of outcome evaluation, we will analyze data from three sources: our naloxone dispensing logs, EMS logs, and hospital admission records. Unfortunately, many of our intended outcomes will not show up in any studies or analyses because unlike the relative ease of access to mortality data regarding death from overdose, data from lives saved from overdose will prove more challenging to collect consistently. Therefore, this data collection must be approached from multiple angles in order to determine if the program is effectively achieving its outcome goals.

By keeping a perpetual inventory of naloxone kits dispensed by the program, at any given time the pharmacists on staff or the Program Director could look at that record and see how many kits have been dispensed to date. This could then be compared to our annual goal of 1,350 kits to determine if we are moving toward our target goal of kits dispensed within the community. If we are meeting or exceeding our goal for number of kits dispensed, we will be able to show that all of our community outreach (including but not limited to advertisements, educational forums, school programs, etc.) was an effective use of our funding.

To analyze the decrease in overdose related death component, we will synthesize data from multiple sources. Because patients will most likely need to utilize EMS to get to an emergency room—as one dose of naloxone will only give them an extra hour or so before overdose symptoms begin again (depending on the half-life of the opioid ingested)—there will be documentation of overdose treatment at area hospitals. We will obtain agreements with hospitals for access to electronic medical record data showing successful overdose reversals or post-reversal treatment at the hospital. In agreement with these hospitals, the patients coming in for overdose will be asked if they used naloxone prior to EMS arrival and if so, where they obtained it from. Patients will be required to sign a release of information to the program in order for us to access their medical records and use them in our research. This component will be discussed when the kit is first dispensed, with the reminder that all information obtained by this program will be used to help demonstrate the effectiveness of it and all personal identifiers will be removed.

We can also collect data from EMS dispatch regarding calls to homes for suspected overdose and whether, prior to EMS arrival, naloxone reversal had been attempted. This would catch cases that utilized hospitals outside of our five county scope of our intervention or if, after EMS arrived and monitored the patient, they determined no further treatment was necessary. Again, EMS personnel would carry those release of information forms with them on their calls and have the patient sign them if they belong to our program.

Within the pharmacy itself, another way to determine if a kit was used to successfully reverse an overdose would be to track repeat visits to the pharmacy by

patients to obtain a naloxone kit refills. If the kit was used, the assumption can be made that overdose reversal was attempted. Each refill initiation will trigger the special counseling mentioned above in process evaluation, and the outcome of that overdose can be documented for outcome evaluation as well.

The trouble with these outcome evaluation measures is that there will be potential inaccuracies with missing data or in some instances, duplicate data regarding use of the kits dispensed. However, these methods will be as effective as possible and give a generalized look at the success of the program.

One final method of outcome evaluation that we will complete annually is to analyze the trends in overdose deaths in the five counties. Again, our target is to decrease those deaths by 46% over the course of three years. Steady downward trends over the duration of the program in overdose mortality in the five intervention counties will be an indicator that an OEND program that increases access to and education about naloxone in these communities is an effective way to combat this crisis.

Five measures that should be added to annual state Behavioral Risk Factor Surveillance System (BRFSS) surveys regarding this topic that may show the effectiveness of the program pre- and post-implementation are as follows:

- 1) Do you know someone who abuses opiates of any kind (heroin, oxycodone, Lortab®, Percocet®, Opana®)?
- 2) Have you ever known someone to be hospitalized or taken by ambulance after suffering an overdose from using a drug not prescribed to them?

- 3) Have you ever known someone who has died from an overdose on one of those substances?
- 4) Have you ever known anyone who keeps a Naloxone kit at home that they got from a pharmacy to use for themselves or a loved one to use to reverse a drug overdose?
- 5) Have you ever known someone who used one of those kits to reverse their overdose and prevent their death?

Ideally, even if the frequencies for question 1 stay constant, questions 2 and 3 may show a decrease, and questions 4 and 5 may show an increase if our program is effective and reaching our target population.

Over the course of the project we hope that the data obtained from these surveys and interviews will help us identify key successes, challenges, and lessons learned with implementation of the program so that other communities can better adapt it. As data comes in every six months in most instances, we can look to see if we are making our goals, and if not, we can continue continuous quality improvement measures under the direction of the Program Director, Research Assistant, and the staff of each pharmacy.

D. CAPACITY OF APPLICANT ORGANIZATION

The Coalition of Kentucky Health Professionals Against Substance Abuse (CKHPASA) encompasses members of varying health professions working in an interdisciplinary manner to tackle the issue of substance abuse in Kentucky. Members of the organization have prior experience educating college students about the risks of substance use through a partnership with the Association of Independent Kentucky

Colleges and Universities. This grant allowed physicians, pharmacists, nurses, social workers, and public health professionals to educate students at colleges averaging 1,000 students in enrollment using evidence-based programs that target initiation of substance abuse in college—particularly stimulants used as study aids.

This program has been distilled to work in high school populations in counties where substance abuse initiation beginning during the teen years is prevalent. That program was adapted and merged with *Media and Me*, which challenges high school students to become more aware of both direct and subtle messaging about alcohol and drug use across multiple media platforms. Therefore, we have experience in adapting and tailoring evidence-based programming.

This hybrid program was presented in counties where teens were significantly at risk for substance abuse initiation. It has been previously taken to Harlan County where presentations were given at Harlan County High School and Harlan High School. Whenever possible in these high school programs, coalition members from the area serve as facilitators for discussion—in fact, there are coalition members in all 120 Kentucky counties, so our reach across the state is broad and impactful—we aren't necessarily "outsiders" coming in to intervene in a community, because a trusted and respected member of the community is there advocating for us.

This program has continued in Harlan County through volunteers who live in the area and are CKHPASA members. Volunteers and educators in the high schools wanted to make sure that this program reached each subsequent incoming freshman class because of its impact on increasing awareness of subtle media messaging involving drugs—particularly the message that "everyone is doing it." There has been a

decrease in substance abuse initiation, particularly with prescription opioids in this population in Harlan County. In fact, of the twelve grant-funded programs we have been a part of since 2010, all twelve continued to be implemented in some form or fashion in their community. We believe this is in no small way due to our members varied backgrounds and their ability to secure funding and resources from outside organizations after grant-funding has ended and to influence the communities they live in that these programs are worth being continued.

CKHPASA has been able to provide training and technical assistance to support other organizations implementing evidence-based programs—particularly in training lay health workers, as we have done in Fayette County in targeting alcohol abuse in minority populations. Our training allowed persons from that minority to group to do significant outreach that our organization could not have done alone.

Performance measure data was collected via surveys administered by the lay health workers in live interviews. Every four months this data was analyzed to see if there were changes in the rates of alcohol consumption in each minority population. In our commitment to continuous quality improvement, this data was used to determine if we needed to make program improvement, and if so, where that needed to take place. If trends were suggesting a decrease in the African-American and Asian-American populations but an increase among the Hispanic population, we would go to the lay health workers we had in the Hispanic community to determine if there was something we could do to improve outreach. After a few tweaks to the education component mostly involving translation, we saw the Hispanic population begin to decrease their alcohol consumption as well.

The mission of the CKHPASA is to use health professionals to reach Kentuckians with information on the dangers associated with substance abuse, and also to provide resources with the goal of sobriety in populations where drug use is prevalent. Health professionals are highly educated and trained in these issues and by bringing in members from different practice types, CKHPASA can offer a full range of education and resources for their target populations. CKHPASA envisions a Kentucky that no longer leads the nation in drug overdose death rates (CDC), but in successful recovery.

In OD-NAP EKY, we are targeting both aims of the vision of CKHPASA and the mission of CKHPASA. By distributing literature with the naloxone kits that explain signs and symptoms of overdose, dangers of unreversed overdose, and the way naloxone works to stop overdose, CKHPASA is educating addicts and their loved ones about the overdose process and helping loved ones make good decisions regarding overdose (e.g., calling an ambulance immediately after administration of naloxone because the addict will likely need at least one more dose). By holding seminars about opiate abuse and overdose at the library, and including resources for recovery in the kits, CKHPASA can help reduce the state's number of substance abusers. The overall goal of the program is to decrease the number of overdose deaths in these communities gripped with devastatingly large losses.

Our board leadership is committed to the goal of reducing drug overdose in these five counties. Dr. Maureen Johnson, who is the Project Director, is a sitting board member and wanted to take on this role because of her passion for removing these access barriers and providing harm reduction in communities with demonstrated need.

Dr. Johnson will be leaving her position as a community pharmacist in order to take on this role. In addition to quarterly meetings at our headquarters in Frankfort, we also hold regional monthly meetings at rotating sites. Our board members wanted this to be a key component of our organization's structure so that leadership could hear from all members of the organization, not just the board or those who could attend the quarterly meeting. Our members listen to their communities and are engaged in helping combat the substance abuse crises that hit closest to home for them.

Because we are of the community we always want to bring community ideas to the table and acquire "champions" from the community to help promote the program and mobilize resources—this is especially key for sustainability components, and the way we have been able to rally our communities around these interventions has meant improved outcomes related to substance abuse throughout the state of Kentucky.

Many organizations experience decreases in membership or high turnover rates as time goes on. We have found that very few of our health professionals get the opportunity to practice in multi-disciplinary settings and that when our members come together for meetings and trainings, they enjoy hearing how the other professions approach problems and look for solutions. They think that approaching the issue of substance abuse from multiple perspectives will provide more holistic and ultimately helpful solutions. After the planning is over and the implementation begins, they enjoy this opportunity to be able to be ambassadors for their communities to help curb substance abuse and then, if the intervention is proven successful, look forward to sharing their success with members in other regions and following up on the success of those disseminations.

Finally, CKHPASA does not and shall not discriminate on the basis of race, color, religion (creed), gender, gender expression, age, national origin (ancestry), disability, marital status, sexual orientation, or military status, in any of its activities or operations. These activities include, but are not limited to, hiring and firing of staff, selection of volunteers and vendors, and provision of services. We are committed to providing an inclusive and welcoming environment for all members of our staff, clients, volunteers, subcontractors, vendors, and clients. If the membership of CKHPASA discovers that any member on an outreach project is in violation of this policy, that member shall be permanently banned from the organization and removed from the project.

E. PARTNERSHIPS AND COLLABORATION

CKHPASA will partner with several organizations throughout the target communities. Because of their existing grassroots work within these communities, we will partner with Hazard Hates Heroin, Jackson Hates Heroin, and Eastern Kentuckians Against Prescription Drug Abuse to help disseminate information about the availability of naloxone and recovery resources in our pharmacies. These organizations were all founded by family members of persons lost to heroin or prescription opiate overdose, and their community forums and local activism target both addicts to get them into treatment but also loved ones of addicts to help them both cope with the emotional toll of caring for an addict. Many of the founding members are also vocal in campaigning in Frankfort for legislative change—the founder of Harlan Hates Heroin was an instrumental voice in lobbying area members of the state General Assembly for some of the provisions of SB 192. We will collaborate with these organizations to hold sessions for addicts and their loved ones to help them become comfortable and confident in

using the Evzio® auto-injectors dispensed by our pharmacies through repeated practice.

For the purposes of these training exercises, we have partnered with Kaléo Pharmaceuticals, the manufacturer of Evzio®. Kaléo, based in Richmond, Virginia, has a philosophy regarding patient-centered care that is unique among pharmaceutical companies. They specialize in medications to assist patients in life saving emergencies and delivery systems for those medications that are patient and caregiver friendly. They have generously donated 50 training devices that may be used 1,000 times each that we can utilize at training sessions.

We will also partner with the local public library in each of the five counties to host forums and information nights. The library is an excellent choice for these events because they will always be free and open to the public and in a “neutral” space. These monthly forums will also address community concerns regarding access to naloxone and will prominently feature trusted community members invested in the program in order to increase acceptance among the communities at large. We know from our prior experience working in this area with high school students in Harlan County that putting people who are familiar with the area and its particular challenges and can offer relatable, specific anecdotes about the region yielded far more successful interactions than those that featured people perceived by the community as “outsiders.”

Partnerships will be continued with the high schools in Harlan County but will also disseminate to the high schools in the other target counties in the first year, with expansion into middle schools by year two. Annual presentations will be given to the students at these schools similarly to past successful programs put on by CKHPASA

surrounding the prescription drug epidemic with tailoring to incorporate and feature heroin. In response to CDC data that exists showing that 5.2% of Kentucky high schoolers have used heroin, the school boards in each county also recognize the need for this program. Education will involve the dangers of abuse (including overdose) from the physical to the financial and social. A significant piece of this program will include information on the availability of take-home naloxone kits in their communities. In addition to those 5.2% of students who are potentially abusing heroin, many more may know classmates, family, or friends that we will have given them the tools to advocate the importance of having naloxone on hand to those loved ones.

Additional partnerships have been secured with the Chambers of Commerce in each county. Member businesses will be a key partner in helping to advertise the program through the placement of flyers and other information regarding the program and the education opportunities at the libraries. Many chamber members have also expressed interest in the program because they have dealt with the consequences of accidental overdose on the premises of their businesses and want to have kits on hand that they can be trained to use by our program's pharmacists. Buy-in from these local community business leaders is critical to increased acceptance in the community.

Perhaps most obviously, we will need to partner our pharmacies with the medical communities in each county. Ideally, we will partner with one physician in each county in order to establish the CCAs necessary to dispense the naloxone kits in our pharmacies. For the purposes of data collection regarding utilization of the kits dispensed by the pharmacy, we will partner with local hospitals. These partners at the hospital will be crucial in helping to determine if patients being admitted for overdose reversal are

patients who had utilized naloxone at home before the ambulance was called, and if that is the case, where they obtained the naloxone from.

F. PROJECT MANAGEMENT

CKHPASA has the personnel to successfully implement and evaluate this project over the three year grant period. In recognizing that the addiction and substance abuse that leads to accidental overdose is a multi-faceted problem, CKHPASA has chosen from its membership a project staff of varied skills and training. Our personnel are trained in public health, pharmacy, social work, and osteopathic medicine and thus bring a variety of perspectives to the issue of harm reduction through OEND.

Dr. Joanne Jefferson, Principal Investigator: Dr. Jefferson has over 24 years of university teaching experience during which she has taught a total of 41 different courses. Currently a professor at Eastern Kentucky University in the Public Health and Health Promotion and Administration departments, she teaches coursework on Drugs, The Individual, and Society and Death & Grief. Dr. Jefferson received her undergraduate and graduate degrees from the University of Wisconsin and her PhD from Purdue University. Dr. Jefferson also currently serves as a board member for the Kentucky Agency for Substance Abuse Policy.

Dr. Jefferson, as our Principal Investigator, will be managing data collection for packaging to our data analyst. Once this process is complete, she will be responsible for writing about the outcomes of the project for publication in the literature. Her background in public health and particularly in the role of how drug use affects not only the individual but their surrounding community and society as a whole will be integral for

her work toward publication. Additionally, as the program is concluding, Dr. Jefferson will speak (alongside Dr. Johnson) to the Kentucky General Assembly in their 2019 session in order to advocate for similar programs like this throughout the state and for Medicaid coverage of Evzio®.

Dr. Maureen Johnson, Project Director: Dr. Johnson is a recent alumnus of the University of Kentucky College of Pharmacy and the University of Kentucky College of Public Health, where she simultaneously earned her PharmD and MPH through the Department of Health Behavior. Her practicum site in preparation for graduation with the MPH was at the Polk Dalton Clinic working with Dr. Mark Cohen in the Subutex® clinic for pregnant women with comorbid opiate addiction. Additionally, she has partnered with Northern Kentucky Hates Heroin to produce media describing the devastation of the heroin epidemic in Kentucky including music videos that have reached thousands online.

Dr. Johnson, serving as our Project Director, will be our main leadership on the ground in the intervention counties. She will be responsible for visiting each site twice monthly starting January 1, 2017. While in the community, she will also lead most of the education sessions at the public libraries and public schools, with assistance from Dr. Schunard. She will also be responsible for the dissemination of sensitivity training at the intervention pharmacies. Additionally, after analysis is complete on semi-annual surveys of pharmacy staff and the community, Dr. Johnson will turn to that data to see where attitudes and perceptions are either not improving or worsening. If either is the case, she will be responsible for leading plans to make changes to the program or its

dissemination to better improve results on performance evaluation measures and thus the success of the program as a whole.

Dr. Mimi Marquez, Project Co-Coordinator: Dr. Marquez holds several positions in the College of Pharmacy at the University of Kentucky, including Director of the Center for the Advancement of Pharmacy Practice (CAPP); Clinical Associate Professor in the Pharmacy Practice and Science Department, and affiliated faculty member in the Institute for Pharmaceutical Outcomes and Policy (IPOP). She received a bachelor of pharmacy degree and a Ph.D. degree from the University of Kentucky, and completed postdoctoral fellowships at the University of Vermont College of Medicine and the UK College of Medicine. Dr. Marquez currently teaches a course through the University of Kentucky College of Pharmacy to train licensed Kentucky pharmacists in naloxone dispensation to earn their state mandated certificates.

Dr. Marquez will primarily be responsible for education and training with our pharmacy staffs. She will teach the course for pharmacists to become naloxone certified through her position at the University of Kentucky College of Pharmacy. She will also assist Dr. Johnson in the sensitivity training of the staff at each pharmacy. She will collaborate with Dr. Jefferson through her role in the Institute for Pharmaceutical Outcomes and Policy in helping shape the post-project publication.

Dr. Roger Davis, Data Analyst: Dr. Davis joined the department of Bioinformatics and Biostatistics at the University of Louisville in 2003 as a statistician with the Statistical Consulting Center. He has a PhD in Applied and Industrial Mathematics, an MSPH in Biostatistics and Decision Science, and a MA in Mathematics all from the

University of Louisville. He has collaborated with 100+ investigators within and outside the University of Louisville. A member of the teaching faculty at the university since 2011, his primary research interest is in survival analysis and generalization of survival data.

Dr. Davis is charged throughout the duration of this project with synthesizing data obtained from our various forms of evaluation. He will do analysis of the results of two different surveys twice yearly and will also analyze data on naloxone utilization and overdose death figures annually. Additionally, he will assist Dr. Jefferson by lending his expertise to the statistical analysis portion of the publication.

Dr. Angel Dumott Schunard, Field Educator: Dr. Schunard is an Associate Professor of Social Work within the Sociology, Social Work, and Criminology department at Morehead State University. She earned her MSW and PhD at the University of Kentucky. Dr. Schnuard's areas of interest are: substance use/abuse, criminal justice system involvement, and treatment-seeking behaviors. She has published in peer-reviewed journals on topics including: substance use/abuse, intimate partner violence, and pregnancy. She is currently the PI for multiple evaluation projects examining outcomes associated with participation in community-based substance abuse treatment services (e.g., Drug Court) funded by the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment.

Dr. Schunard's experience in social work and in substance abuse treatment will make her an asset for developing our brochure of resources to be inserted in each naloxone kit. Additionally, Dr. Schunard will assist Dr. Johnson with the development of

the educational components of our program in local high schools and at public libraries and any materials disseminated in those programs.

Benjamin Coffin III, Research Assistant: Mr. Coffin is a Doctor of Osteopathy student at the Kentucky College of Osteopathy in Pikeville. Mr. Coffin has a particular interest in addiction medicine and has been involved in research projects on campus studying the variance in dosage leading to overdose events using morphine in rats.

Mr. Coffin's proximity to the area compared to the rest of the staff will make him essential for quick response to emergent situations. His main role will be in compiling data on prescription naloxone dispensing at each of the local pharmacies by looking at monthly dispensing snapshots to ensure that the program is functioning at the desired level of operation. By making those analyses monthly, Mr. Coffin will be able to see areas for improvement much more quickly and any necessary changes regarding recruitment or advertising could be implemented at sites showing need for improvement.

The project management team will meet quarterly at CKPHASA headquarters in Frankfort, Kentucky. In those times where the team is not meeting in person, group e-mails and text messages will be utilized so that any important feedback, particularly if it is determined that outcome or implementation goals are not being met, can be addressed before the next quarterly meeting.

Annual professional development meetings will be held in January for the team at CKPHASA headquarters. Additionally, participation of the project management teams in their regional monthly CKPHASA meetings which will continue to provide training on

achieving the missions of the organization in educating their local communities on substance abuse related policies and initiatives. By remaining active in CKPHASA, our project management team will be exposed to the latest evidence-based education approaches throughout the health disciplines and will be kept abreast of changing state policy and legislation that may impact the various programs and projects being implemented by our members across the state of Kentucky. This involvement in a fun, positive, enriching environment will help us ensure little to no staff turnover and increased staff engagement.

By utilizing CKPHASA resources, especially members of the organization as members of our project management team and community partners, we will be able to sustain this program in the communities targeted in this intervention. The training and feedback those members provide to the organization will be essential for CKPHASA members residing in all 120 Kentucky counties to disseminate the successful program across the state of Kentucky.

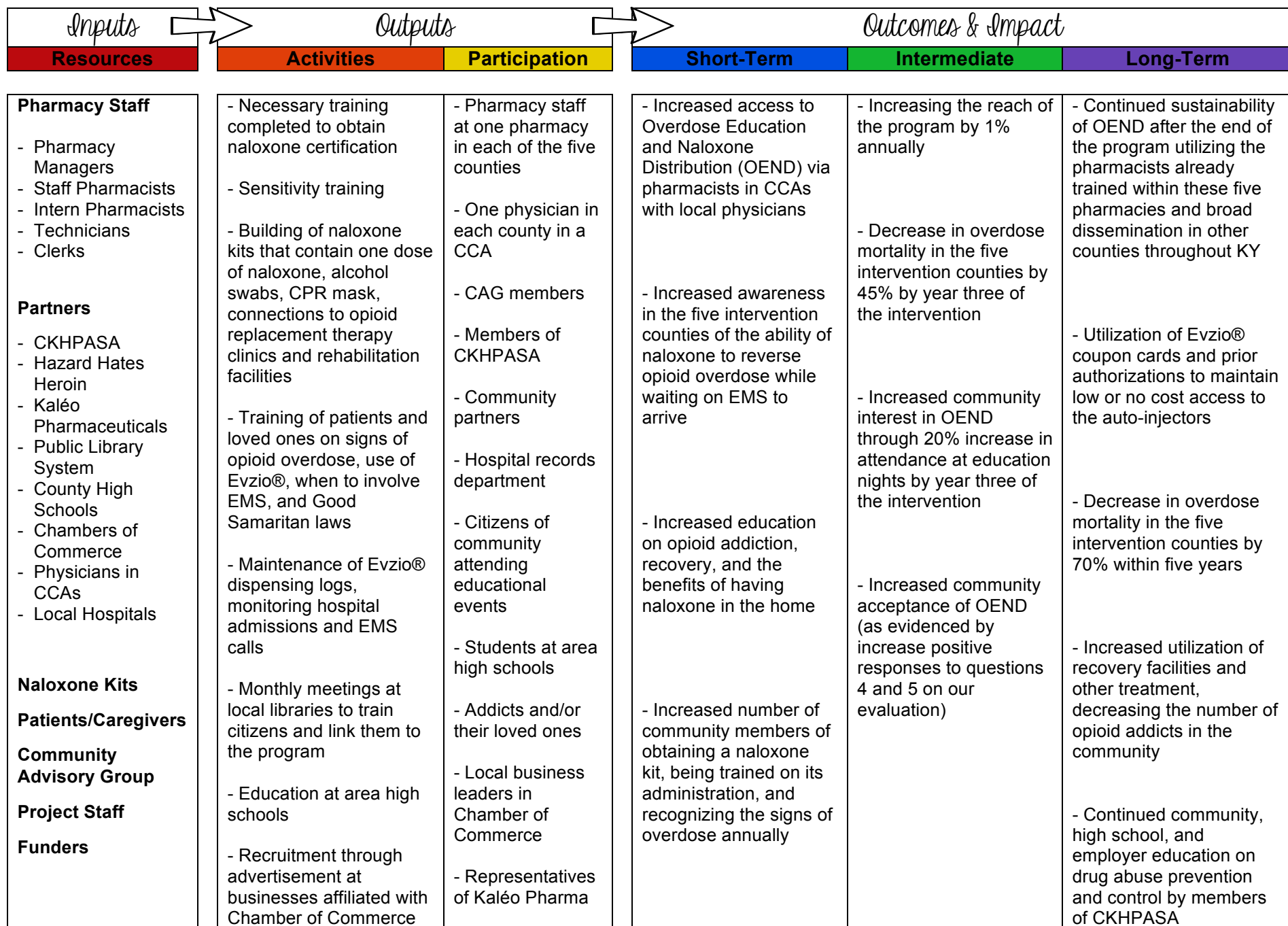
References

1. Drug Abuse 2013 data for Kentucky. *Trust for America's Health*. Available at: <http://healthyamericans.org/reports/drugabuse2013/release.php?stateid=ky>. Accessed April 2, 2016.
2. Heroin Use and Prescription Drug Misuse in Kentucky. *Kentucky Health Issues Poll 2014*. Available at: <http://www.healthy-ky.org/sites/default/files/KHIPdrugmisuseFINAL.pdf>. Accessed April 2, 2016.
3. 2013 Overdose Fatality Report. *Kentucky Office of Drug Control Policy*. Available at: <http://odcp.ky.gov/Reports/2013ODCPOverdoseDeathReportfinal1.pdf>. Accessed April 2, 2016.
4. Senate Bill 192. *Kentucky State Legislature*. Available at: <http://www.lrc.ky.gov/record/15rs/SB192.htm>. Accessed April 2, 2016.
5. KRS 217.186. *Kentucky Revised Statutes*. Available at: <http://www.lrc.ky.gov/statutes/statute.aspx?id=44004>. Accessed April 2, 2016.
6. The Heroin Epidemic. *Kentucky Office of Drug Control Policy*. Available at: <http://odcp.ky.gov/Pages/The-Heroin-Epidemic.aspx>. Accessed April 2, 2016.
7. County Level Data Sets: Poverty. *USDA ERS*. Available at: <http://www.ers.usda.gov/data-products/county-level-data-sets/poverty.aspx>. Accessed April 2, 2016.
8. Local Area Unemployment Statistics Map. *Bureau of Labor Statistics*. Available at: <http://data.bls.gov/map/MapToolServlet>. Accessed April 2, 2016.
9. Drug Abuse and Mental Disorders: Cormorbidity is Reality. *National Institute on Drug Abuse*. Available at: https://archives.drugabuse.gov/NIDA_Notes/NNVol14N4/DirRepVol14N4.html. Accessed April 2, 2016.
10. County Health Rankings 2015. *County Health Rankings*. Available at: <http://www.countyhealthrankings.org/app/kentucky/2015/overview>. Accessed April 2, 2016.
11. HPSA Find. *Health Resources and Services Administration*. Available at: <http://datawarehouse.hrsa.gov/tools/analyzers/HpsaFindResults.aspx>. Accessed April 2, 2016.
12. Kentucky Drug Control Update. *National Office of Drug Control Policy*. Available at: https://www.whitehouse.gov/sites/default/files/docs/state_profile-kentucky.pdf. Accessed April 2, 2016.
13. Heroin Addicts Threaten to Overwhelm Agencies. *Courier-Journal*. Available at: <http://www.courier-journal.com/story/news/investigations/2014/05/16/heroin-addicts-threaten-overwhelm-agencies/2140760/>. Accessed April 2, 2016.
14. Quickfacts. *United States Census Bureau*. Available at: <http://www.census.gov/quickfacts/>. Accessed April 2, 2016.
15. Reducing Opioid Overdose Through Education and Naloxone Distribution. *American Public Health Association*. Available at: <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy->

- database/2014/07/16/13/08/reducing-opioid-overdose-through-education-and-naloxone-distribution. Accessed April 2, 2016.
16. Naloxone monograph. Lexi-Comp Lexi Drugs. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/7338. Accessed April 2, 2016.
 17. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time-series analysis. *The BMJ*. Available at: <http://www.bmj.com.ezproxy.uky.edu/content/346/bmj.f174>. Accessed April 2, 2016.
 18. Naloxone kits and naloxone autoinjectors. *Veterans Affairs Pharmacy Benefits Manager*. Available at: http://www.pbm.va.gov/PBM/clinicalguidance/clinicalrecommendations/Naloxone_Kits_and_Autoinjector_Recommendations_for_Use_Rev_Oct_2015.pdf. Accessed April 2, 2016.
 19. ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling. *American Society of Health-System Pharmacy*. Available at: <http://www.ashp.org/doclibrary/bestpractices/orggd/pteduc.aspx>. Accessed April 2, 2016.
 20. Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduction Journal*. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4527253/>. Accessed April 2, 2016.
 21. Getting to Outcomes. *RAND*. Available at: <http://www.rand.org/health/projects/getting-to-outcomes.html>. Accessed April 2, 2016.
 22. State and County Estimates of Low Literacy. *National Center for Education Statistics*. Available at: <https://nces.ed.gov/naal/estimates/StateEstimates.aspx>. Accessed April 2, 2016.
 23. Evzio® Patient Information Sheet. *Kaléo Pharmaceuticals*. Available at: <http://evzio.com/pdfs/Evzio-Patient-Information.pdf>. Accessed April 2, 2016.
 24. Health Information Privacy. *Department of Health and Human Services*. Available at: <http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>. Accessed April 2, 2016.
 25. KRS 218A.133. *Kentucky Revised Statutes*. Available at: <http://www.lrc.ky.gov/statutes/statute.aspx?id=44007>. Accessed April 2, 2016.
 26. Factors Associated with Participation in Cancer Prevention and Control Studies Among Rural Appalachian Women. *Family and Community Health*. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086267/>. Accessed April 29, 2016.
 27. Strategies Guided by Best Practice for Community Mobilization. *Advocates for Youth*. Available at: http://advocatesforyouth.org/storage/advfy/documents/Factsheets/strategies%20guided%20by%20best%20practice_8-11-14.pdf. Accessed April 2, 2016.

28. The Heroin Antidote? How Naloxone Can Help and Hurt Addicts. *The Huffington Post*. Available at: http://www.huffingtonpost.com/jamison-monroe-jr/addiction-and-recovery_b_5563730.html. Accessed April 2, 2016.
29. Drugs, Brains, and Behavior: The Science of Addiction. *The National Institutes on Drug Abuse*. <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/treatment-recovery>. Accessed April 29, 2016.

Appendix A Logic Model



Appendix B Work Plans

Work Plan #1
June 1, 2016 – December 31, 2016

Grantee Name CKHPASA

Funds Requested \$750,000

Goal I: Pharmacy staff at each of the five pilot pharmacies to initiate naloxone kit dispensing on January 1, 2017.		
Objective I: All pharmacists at each of the five pilot pharmacies to obtain naloxone certification and all staff members at the pharmacy to complete the developed sensitivity training program within the first six months of the grant period and adapt dispensing model to allow accurate record keeping of naloxone distribution.		
Rationale for Objective I: State law mandates that all pharmacists who want to dispense naloxone secondary to a CCA with a physician must receiving training and certification through the Kentucky Board of Pharmacy. Due to the rurality of the pharmacies, sensitivity training must be completed to ensure HIPAA is being followed and addicts and their loved ones are not being stigmatized for seeking help.		
Measures of Accomplishment for Objective I: a. Naloxone certifications distributed by the Kentucky Board of Pharmacy to each staff pharmacist. b. Each pharmacy staff member completing a post sensitivity training questionnaire. c. Naloxone dispensing logs created and bound.		
Activities in support of Objective I: a. Training trips to the University of Kentucky College of Pharmacy for staff pharmacists to obtain certification. b. Creation of naloxone log by each pharmacy. c. Sensitivity training events hosted at each of the five implementing pharmacies for entire staff.	Person/agency responsible for Accomplishing Activities: a. Mimi Marquez, Project Co-Coordinator b. Maureen Johnson, Project Director / Pharmacy Managers c. Maureen Johnson, Project Director / Mimi Marquez, Project Co-Coordinator	Activity Timeline: a. By November 1, 2016 to allow for ease of scheduling. b. By December 1, 2016 to allow changes to be made to the log if necessary. c. By December 31, 2016, one session at each pharmacy hosted at a time convenient to staff.

Appendix B Work Plans

Work Plan #2
January 1, 2017 – May 31, 2019

Grantee Name CKHPASA

Funds Requested \$750,000

Goal I: Increase in the number of naloxone kits dispensed to addicts or their loved ones annually.		
Objective I: Kits dispensed to 1% of the total populations of all five counties annually (1,350) for a total of 3,375 kits dispensed in the thirty months of post-planning program implementation, between January 1, 2017 and May 31, 2019.		
Rationale for Objective I: Because an estimated 30% of the community will know someone actively addicted to opiates but because there will be overlap in the known addict, we want to target about 10% of the community for the overdose education component but we expect to only serve about 1% of the total population annually with overdose kits. This is because each addict in the community might have several family members but only one kit would be needed in that instance. There may also be a stigma component in seeking the kits because of the small town atmosphere and worry that other community members would “find out” you or a loved one was on drugs, which may reduce the number of persons actually obtaining kits.		
Measures of Accomplishment for Objective I: a. Naloxone distribution across all five counties meets or exceeds the goal of 3,375 kits dispensed by May 31, 2019. b. Year end total for 2017 meeting or exceeding 1,350 kits. c. Year end total for 2018 meeting or exceeding 2,700 kits.		
Activities in support of Objective I: a. In-pharmacy and community advertisement (through Chamber of Commerce) of the availability of our OEND program. b. Annual education in each high school of the target counties about OEND and addiction. c. Community education nights and forums to teach community members about OEND and addiction.	Person/agency responsible for Accomplishing Activities: a. Maureen Johnson, Project Director / Staff Pharmacists / Chamber of Commerce Members b. Maureen Johnson, Project Director / Angel Dumott Schunard, Field Educator c. Maureen Johnson, Project Director / CKPHASA / Angel Schunard, Field Educator	Activity Timeline: a. Beginning before implementation in late December 2016 and lasting until May 2019. b. Each year in the Spring Semester, beginning in Spring 2017 and continuing until Spring 2019. c. Beginning January 1, 2017 once monthly in the public library of each county through May 31, 2019.

Appendix B Work Plans

Work Plan #3
January 1, 2017 – May 31, 2019

Grantee Name CKHPASA

Funds Requested \$750,000

Goal I: Decrease opioid overdose mortality in each intervention county.		
Objective I: Overdose deaths in the five intervention counties decreased by 45% before the culmination of the grant period on May 31, 2019, with a steadily decreasing number of annual deaths over the course of the project.		
Rationale for Objective I: By targeting the population that needs this intervention most and with increasing numbers of kits dispensed annually, and because these targets match “high implementer” communities in the Massachusetts OEND program, we expect to see a similar decrease in opioid overdose related death in the five intervention counties as the Massachusetts program saw over a similar timeframe.		
Measures of Accomplishment for Objective I: a. Analysis of opioid overdose deaths in the community showing a continued downward trend in the number of overdose deaths. b. Hospital/EMS records and Evzio® refill records indicating that the number of those surviving overdose is increasing. c. Increased community awareness of the positive outcomes of OEND by increased positive response on the community evaluation survey with the number of positives responses increasing annually.		
Activities in support of Objective I: a. Annual analysis of overdose death mortality reported in each of the five counties. b. Annual analysis of Hospital/EMS records and pharmacy refill records compared to number of kits dispensed. c. Annual implementation survey of the community at large to assess community acceptance of the OEND program.	Person/agency responsible for Accomplishing Activities: a. Roger Davis, Data Analyst b. Maureen Johnson, Project Director / Roger Davis, Data Analyst / Benjamin Coffin III, Research Assistant c. Maureen Johnson, Project Director / Roger Davis, Data Analyst / Benjamin Coffin III, Research Assistant	Activity Timeline: a. Reports due annually, final cumulative report and analysis of project duration trends due on May 31, 2019. b. Quarterly totals due beginning March 1, 2017 with annual analysis synthesizing data due in January of each year and final report due on May 31, 2019. c. Surveys performed annually in December and data analyzed from those surveys by January 31 of the following year. Final program duration analysis due on May 31, 2019.

Appendix C Budget and Justification

Budget Item	Year One	Year Two	Year Three	Project Totals
Salary/Wages	\$191,000	\$202,651	\$221,077	\$614,728
Fringe Benefits	\$66,829	\$69,999	\$74,627	\$211,455
Naloxone Kits	\$348,395	\$348,395	\$348,395	\$1,045,185
Equipment/Supplies	\$4,000	\$2,000	\$2,000	\$8,000
Travel	\$23,664	\$33,664	\$33,664	\$90,992
Other	\$55,000	\$50,000	\$45,000	\$150,000
Annual Totals	\$688,888	\$706,709	\$724,763	<u>\$2,120,360</u>

A. Salaries and Wages

Project Member	Position	Year One			Year Two			Year Three		
		Salary	Effort	Amount Requested	Salary	Effort	Amount Requested	Salary	Effort	Amount Requested
Dr. Joanne Jefferson	Principal Investigator	\$80,000	20%	\$16,000	\$85,296	20%	\$17,059	\$93,671	20%	\$18,734
Dr. Maureen Johnson	Project Director	\$85,000	100%	\$85,000	\$90,627	100%	\$90,627	\$99,526	100%	\$99,526
Dr. Mimi Marquez	Project Co-Coordinator	\$100,000	35%	\$35,000	\$106,620	35%	\$37,317	\$117,089	35%	\$40,981
Dr. Roger Davis	Data Analyst	\$60,000	20%	\$12,000	\$63,972	20%	\$12,794	\$70,253	20%	\$14,051
Dr. Angel Dumott Schunard	Field Educator	\$70,000	40%	\$28,000	\$74,634	40%	\$29,854	\$81,962	40%	\$32,785
Benjamin Coffin III	Research Assistant	\$15,000*	100%	\$15,000	\$15,000*	100%	\$15,000	\$15,000*	100%	\$15,000
Annual Totals				\$191,000			\$202,651			\$221,077

Total, Salaries and Wages: \$614,728

Principal Investigator, Dr. Joanne Jefferson (20%, 2.4 months, Years 1-3) – Dr. Jefferson has over 24 years of university teaching experience during which she has taught a total of 41 different courses. Currently a professor at Eastern Kentucky University in

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the Public Health and Health Promotion and Administration departments, she teaches coursework on Drugs, The Individual, and Society and Death & Grief. Dr. Jefferson received her undergraduate and graduate degrees from the University of Wisconsin and her PhD from Purdue University. Dr. Jefferson also currently serves as a board member for the Kentucky Agency for Substance Abuse Policy.

Dr. Jefferson, as PI, will be devoting 20% effort annually to the project. She will be responsible for all aspects of the project and will be managing data collection for packaging to our data analyst. Once this process is complete, she will be responsible for writing about the outcomes of the project for publication in the literature. Her background in public health and particularly in the role of how drug use affects not only the individual but their surrounding community and society as a whole will be integral for her work toward publication. Additionally, as the program is concluding, Dr. Jefferson will speak (alongside Dr. Johnson) to the Kentucky General Assembly in their 2019 session in order to advocate for similar programs like this throughout the state and for Medicaid coverage of Evzio®.

Project Director, Dr. Maureen Johnson (100%, 12 months, Years 1-3) – Dr. Johnson is a recent alumnus of the University of Kentucky College of Pharmacy and the University of Kentucky College of Public Health, where she simultaneously earned her PharmD and MPH through the Department of Health Behavior. Her practicum site in preparation for graduation with the MPH was at the Polk Dalton Clinic working with Dr. Mark Cohen in the Subutex® clinic for pregnant women with comorbid opiate addiction. Additionally, she has partnered with Northern Kentucky Hates Heroin to produce media describing the devastation of the heroin epidemic in Kentucky including music videos that have reached thousands online.

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Budget and Justification

Dr. Johnson will be completely grant funded for the duration of the project. She will be our main leadership on the ground in the intervention counties. She will be responsible for visiting each site twice monthly starting January 1, 2017. While in the community, she will also lead most of the education sessions at the public libraries and public schools, with assistance from Dr. Schunard. She will also be responsible for the dissemination of sensitivity training at the intervention pharmacies. Additionally, after analysis is complete on semi-annual surveys of pharmacy staff and the community, Dr. Johnson will turn to that data to see where attitudes and perceptions are either not improving or worsening. If either is the case, she will be responsible for leading plans to make changes to the program or its dissemination to better improve results on performance evaluation measures and thus the success of the program as a whole.

Project Co-Coordinator, Dr. Mimi Marquez (35%, 4.2 months, Years 1-3) – Dr. Marquez holds several positions in the College of Pharmacy at the University of Kentucky, including Director of the Center for the Advancement of Pharmacy Practice (CAPP); Clinical Associate Professor in the Pharmacy Practice and Science Department, and affiliated faculty member in the Institute for Pharmaceutical Outcomes and Policy (IPOP). She received a bachelor of pharmacy degree and a Ph.D. degree from the University of Kentucky, and completed postdoctoral fellowships at the University of Vermont College of Medicine and the UK College of Medicine. Dr. Marquez currently teaches a course through the University of Kentucky College of Pharmacy to train licensed Kentucky pharmacists in naloxone dispensation to earn their state mandated certificates.

Dr. Marquez, at 35% effort, will mainly be responsible for education and training with our pharmacy staffs. She will teach the course for pharmacists to become naloxone certified through her position at the University of Kentucky College of Pharmacy. She will also

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assist Dr. Johnson in the sensitivity training of the staff at each pharmacy. She will collaborate with Dr. Jefferson through her role in the Institute for Pharmaceutical Outcomes and Policy in helping shape the post-project publication.

Data Analyst, Dr. Roger Davis (20%, 2.4 months, Years 1-3) – Dr. Davis joined the department of Bioinformatics and Biostatistics at the University of Louisville in 2003 as a statistician with the Statistical Consulting Center. He has a PhD in Applied and Industrial Mathematics, an MSPH in Biostatistics and Decision Science, and a MA in Mathematics all from the University of Louisville. He has collaborated with 100+ investigators within and outside the University of Louisville. A member of the teaching faculty at the university since 2011, his primary research interest is in survival analysis and generalization of survival data.

Dr. Davis, at 20% effort for all three years, will be charged throughout the duration of this project with synthesizing data obtained from our various forms of evaluation. He will do analysis of the results of two different surveys twice yearly and will also analyze data on naloxone utilization and overdose death figures annually. Additionally, he will help Dr. Jefferson by lending his expertise to the statistical analysis portion of the publication.

Field Educator, Dr. Angel Dumott Schunard (40%, 4.8 months, Years 1-3) – Dr. Schunard is an Associate Professor of Social Work within the Sociology, Social Work, and Criminology department at Morehead State University. She earned her MSW and PhD at the University of Kentucky. Dr. Schunard's areas of interest are: substance use/abuse, criminal justice system involvement, and treatment-seeking behaviors. She has published in peer-reviewed journals on topics including: substance use/abuse, intimate partner violence, and pregnancy. She is currently the PI for multiple evaluation projects examining outcomes associated with participation in

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community-based substance abuse treatment services (e.g., Drug Court) funded by the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment.

Dr. Schunard's experience in social work and in substance abuse treatment will make her an asset for developing our brochure of resources to be inserted in each naloxone kit. Additionally, Dr. Schunard will assist Dr. Johnson with the development of the educational components of our program in local high schools and at public libraries and any materials disseminated in those programs. These activities will take an anticipated annual 40% effort.

Research Assistant, Benjamin Coffin III – Mr. Coffin is a Doctor of Osteopathy student at the Kentucky College of Osteopathy in Pikeville. Mr. Coffin has a particular interest in addiction medicine and has been involved in research projects on campus studying the variance in dosage leading to overdose events using morphine in rats.

Mr. Coffin's proximity to the area compared to the rest of the staff will make him essential for quick response to emergent situations. His main role will be in compiling data on prescription naloxone dispensing at each of the local pharmacies by looking at monthly dispensing snapshots to ensure that the program is functioning at the desired level of operation. By making those analyses monthly, Mr Coffin will be able to see areas for improvement much more quickly and any necessary changes regarding recruitment or advertising could be implemented at sites showing need for improvement. Mr. Coffin will not receive a salary, but wages at a level of \$15 per hour, 20 hours per week, for 50 weeks of the year.

Appendix C Budget and Justification

B. Fringe Benefits

		Year One	Year Two	Year Three
<i>Project Member</i>	<i>Position</i>	<i>Fringe Requested</i>	<i>Fringe Requested</i>	<i>Fringe Requested</i>
Dr. Joanne Jefferson	Principal Investigator	\$5,549	\$5,839	\$6,261
Dr. Maureen Johnson	Project Director	\$28,807	\$30,326	\$32,548
Dr. Mimi Marquez	Project Co-Coordinator	\$11,198	\$11,803	\$12,698
Dr. Roger Davis	Data Analyst	\$4,699	\$4,932	\$5,266
Dr. Angel Dumott Schunard	Field Educator	\$10,248	\$10,771	\$11,526
Benjamin Coffin III	Research Assistant	\$6,328	\$6,328	\$6,328
Annual Totals		\$66,829	\$69,999	\$74,627

Total, Fringe Benefits: \$211,455

Personnel fringe costs were based on the following benefits schedule, which can also be found at <http://www.research.uky.edu/ospa/info.html>. Fringe benefits are escalated as described in the link. Fringe benefits are requested as prorated based on the percentage of salary/wage support requested, as described above.

C. Naloxone Kits

Contents	Annual Cost
Evzio® Auto-injector, 1	\$330,750
CPR Mask, 1	\$17,482
Latex Gloves, 1 pair	\$139
Alcohol Swabs, 2	\$24
Total Kit Cost	\$348,395

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Total, Naloxone Kits: \$1,045,185

Each naloxone kit will contain one Evzio® auto-injector, one CPR mask, one pair of latex gloves, and two alcohol swabs. 1,350 kits will be dispensed annually, with a per kit cost of: \$245, Evzio®; \$12.95, CPR mask; \$0.10 one pair of latex gloves; \$0.02 two alcohol swabs. The kit will additionally contain paper literature, which is included in the supply budget.

While other forms of naloxone were about half the price of Evzio®, Kaléo Pharmaceuticals has given the program a bulk-buy discount. We also think the benefits of the auto-injectors in helping reducing stress and ensure proper administration during an overdose situation is a critical component to analyze when assessing the cost of the product.

D. Equipment and Supplies

Items Requested	Year One Cost	Year Two Cost	Year Three Cost
Laptop Computer	\$2,000		
Office Supplies	\$2,000	\$2,000	\$2,000
Total Cost	\$4,000	\$2,000	\$2,000

Total, Equipment and Supplies: \$8,000

Appendix C Budget and Justification

Computer laptop for Project Coordinator: \$2,000, year one only. Because many hours of the week will be spent on the road and in the field, the Project Director requests a reliable laptop that will be able to obtain strong signals in disadvantageous locations and will also make it easier for her to synthesize data from multiple outreach points.

Office Supplies: \$2,000 annually. Supplies are needed to create the literature that is distributed with each naloxone kit and will also be needed on the ground at each pharmacy for maintenance of proper dispensing logs. These supplies include: copy paper, printer paper, printer cartridges, binders, tabs, Ziploc® bags.

E. Travel

	Year One	Year Two	Year Three
Mileage	\$21,664	\$21,664	\$21,664
Overnights	\$2,000	\$2,000	\$2,000
Conferences		\$10,000	\$10,000
Annual Totals	\$23,664	\$33,664	\$33,664

Total, Travel: \$90,992

In-state travel: Project Director to travel to intervention counties from Frankfort, Kentucky twice weekly for the duration of the grant. 38,688 miles annually traveled, 116,064 miles traveled over the duration of the grant, at \$0.56 federal mileage reimbursement rate; total \$64,996. Additionally, up to twenty overnight stays in the region for the Project Director annually at \$100 a night when leading the education programs at schools in lieu of an additional weekly trip to the intervention area.

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Out-of-state travel: Project Director to attend the American Pharmacists Association (APhA) Annual Meetings in Atlanta, Georgia. Budget for airfare, four nights in a hotel room, and per diem while attending the meeting.

F. Other

	Year One	Year Two	Year Three
Evaluation Surveys	\$15,000	\$15,000	\$15,000
Pharmacy Incentives	\$25,000	\$25,000	\$25,000
Community Advertising	\$15,000	\$10,000	\$5,000
Annual Totals	\$55,000	\$50,000	\$45,000

Total, Other: \$150,000

Evaluation surveys will be administered twice annually. One will target the attitudes of pharmacy staff on implementation and thus only around one hundred people with each administration. The other will target 25,000 community members (5,000 in each county with each administration. In order to produce and administer these surveys, which will help to make changes as quickly as possible to program implementation, we will need to cover the cost of administration. We expect this cost to be \$7,500 each time the surveys are administered, at a cost of \$15,000 annually.

Pharmacy incentives will be provided at an annual rate of \$5,000 for each of the five pharmacies implementing our program. This is because as our daily implementation staff, they will be adding this project to their already busy workload. To compensate them, this

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will be given to the pharmacy manager annually and they can use it however they see fit to better serve their general patient population and the participants in this program.

Community advertising will be especially key in the first year of the program, tapering off as the program progresses but with still meaningful and impactful advertising. The first year of advertising created will be high quality and we will collaborate with our community partners in order to reach as many people as possible. These advertisements will focus mainly on the existence of the program. Gradually funding will decrease and an emphasis in advertising the successes of the program will be a key focus will begin to supplant general program knowledge advertisement.